REMARKS

The Office Actions mailed July 17, 2005, November 23, 2005, and March 21, 2006 and references cited therein have been reviewed. Applicants have canceled claims 1-58 and added new claims 59-115. Applicants resubmitted all the amendments since the previous two Amendments were deemed non-responsive, thus appear to not have been entered. Applicants submit that the amendments to the specification do not constitute new matter.

NON-RESPONSIVE OBJECTION

The Examiner indicated in the Office Action mailed November 23, 2005 and March 21, 2006 that the Amendment filed on September 16, 2005 was not fully responsive. Although Applicants respectfully disagree, Applicants have made a good faith attempt to respond to the objections raised by the Examiner.

A. Section 102 and 103 Arguments

The Examiner asserted in the Office Action mailed November 23, 2005 that the response by Applicants must present arguments pointing out the specific distinctions believed to render the claims patentable over the cited art of record. Applicants submit that the arguments under the subheadings "THE 102 REJECTION" and "THE 103 REJECTION" include detailed arguments regarding the patentability of the newly submitted claims.

Applicants sincerely believe that the arguments for patentability of the new pending claims is a "*bona fide* attempt to advance the application" to allowance. Applicants note that the Examiner did not raise this objection in the Office Action mailed November 23, 2005, thus believe that the Examiner has acknowledged that the Section 102 and 103 rejections were fully addressed by Applicants. Applicant also contacted Corrine McDermott on May 5, 2006 to obtain information regarding the Section 102 and 103 arguments. Ms. McDermott acknowledged that Applicants

appeared to have addressed the Section 102 and 103 arguments in the Amendment filed on December 19, 2005.

Applicants have fully responded to the Examiner's request to supply arguments regarding the Section 102 and 103 rejections.

B. Support for the Claim Amendments

The Examiner also asserted that Applicants must indicate where support for the amendments to the claims is found in the specification. Applicants contacted Ms. McDermott regarding this matter. After reviewing the Examiner's notes, Ms. McDermott could not determine which limitations in the claims the Examiner had an objection. Ms. McDermott indicated that the Examiner may have been inquiring about support for the five (5) elements of the claims raised by Applicants which address the Section 102 rejection. In an effort to assist the Examiner in locating support for the claim elements set forth in new claims 59 to 115. Applicant submits that the reference to a particular original claim, figure or page in the specification for the claim elements below are not necessarily the only support for such limitation in the originally filed application.

Claim Limitation Citations

59. A flexible vascular graft for connecting to a blood vessel (P. 6, ln. 24 - P. 7, ln.9, Original claim2 1 & 41), said vascular graft comprising a flexible wall that forms a passageway for blood flow through the vascular graft (P. 6, ln. 24 - P. 7, ln.9), a first drug layer at least partially coated on an inner surface of said flexible wall and an inner layer (P. 13, ln. 15-26; Figure 1, Original claims 1 & 2), said inner layer formed of a porous material designed to promote endothelialization (P. 15, lns. 22-29), said first drug layer including at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer (P. 4, lns. 16-26; P. 13, ln. 15-26; Figure 1, Original claims 1 & 2), said

amphiphilic block copolymer having a structure that controllably releases up to about 90 percent of at least one of said drugs into said inner layer within about thirty days of being connected to the blood vessel (P. 14, lns. 8-17; Original claim 2), said amphiphilic block copolymer including a network including both hydrophobic and hydrophilic polymer chains that can swell in both hydrophobic and hydrophilic solvents (Original claim 1), said at least one drug formulated to inhibit stenosis, vascular narrowing, thrombosis or combinations thereof (Original claim 2).

60. The flexible vascular graft as defined in claim 59, wherein said flexible wall includes a biostable fabric material, said biostable fabric material including a material selected from the group consisting of polyester, polytetrafluoroethylene, polyurethane, polysilicones, poly(meth)acrylates, polyalkyl oxides, polyvinyl alcohols, polyalkylene glycols, polyvinyl pyrrolidone or combinations thereof. (P. 7, lns. 10-17).

61. The flexible vascular graft as defined in claim 59, wherein said amphiphilic block copolymer includes macromolecular mers of polyethylene glycol, poly(isobutylene), and poly(dimethylsiloxane). (P. 10, lns.6-14).

62. The flexible vascular graft as defined in claim 60, wherein said amphiphilic block copolymer includes macromolecular mers of polyethylene glycol, poly(isobutylene), and poly(dimethylsiloxane). (P. 10, lns.6-14).

63. The flexible vascular graft as defined in claim 59, wherein said inner layer

includes collagen. (Original claim 26).

64. The flexible vascular graft as defined in claim 62, wherein said inner layer includes collagen. (Original claim 26).

65. The flexible vascular graft as defined in claim 59, wherein the drug in said first drug layer includes trapidil and GM-CSF. (P. 11, ln. 19 - P. 13, ln. 26).

66. The flexible vascular graft as defined in claim 64, wherein the drug in said first drug layer includes trapidil and GM-CSF. (P. 11, ln. 19 - P. 13, ln. 26).

67. The flexible vascular graft as defined in claim 59, including a barrier layer to inhibit release of at least one of said drugs from said first drug layer into said inner layer, said barrier layer including parylene or a derivative thereof. (P. 14, ln. 24 - P. 15, ln. 4).

68. The flexible vascular graft as defined in claim 66, including a barrier layer to inhibit release of at least one of said drugs from said first drug layer into said inner layer, said barrier layer including parylene or a derivative thereof. (P. 14, ln. 24 - P. 15, ln. 4).

69. The flexible vascular graft as defined in claim 59, wherein said amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of said drugs from said first drug layer into said inner layer within about six hours of

being connected to the blood vessel. (Original claim 16).

70. The flexible vascular graft as defined in claim 59, including a first penetration barrier layer to inhibit penetration of blood through said vascular graft. (P. 15, lns. 24-25).

71. The flexible vascular graft as defined in claim 68, including a first penetration barrier layer to inhibit penetration of blood through said vascular graft. (P. 15, lns. 24-25).

72. The flexible vascular graft as defined in claim 59, including a second drug layer positioned on said vascular graft to release at least one drug into tissues surrounding said vascular graft. (P. 15, lns. 25-26).

73. The flexible vascular graft as defined in claim 71, including a second drug layer positioned on said vascular graft to release at least one drug into tissues surrounding said vascular graft. (P. 15, lns. 25-26).

74. The flexible vascular graft as defined in claim 72, wherein at least one drug in said second drug layer is not included in said first drug layer. (P. 14, ln. 18-23).

75. The flexible vascular graft as defined in claim 72, including a drug barrier layer to inhibit release of at least one drug from said second drug layer. (P. 14, ln. 24 - P. 15, ln. 4, See Figure 1).

76. (New) The flexible vascular graft as defined in claim 74, including a drug barrier layer to inhibit release of at least one drug from said second drug layer.

Claims 77-91. (See citations for limitations as set forth in claims 59-76).

92. (New) The stent as defined in claim 77, wherein teeth or other indentations that are part of a ratcheting mechanism. (Original claim 40).

Claims 93-111. (See citations for limitations as set forth in claims 59-76).

112. The method as defined in claim 94, wherein said stent includes teeth or other indentations, and including the step of using a ratcheting mechanism to expand said stent in said blood vessel. (Original claim 40).

113. (New) The method as defined in claim 93, wherein at least one of said drugs in said first drug layer is at least partially contained in microparticles of said amphiphilic block copolymer, said microparticles having a size of up to about 10 micrometers. (P. 16, ln. 24-27).

114. (New) The method as defined in claim 115, wherein said microparticles of said amphiphilic block copolymer are at least partially dispersed in hydrogel. (P. 5, lns. 14-17).

115. (New) The method as defined in claim 93, including the step of administering at least one drug to the patient either orally or intravenously. (Original claim 47).

OBJECTIONS TO CLAIMS AND SPECIFICATION

Claim 41 was objected to for not including the proper punctuation. Applicants have canceled claim 41 thereby making the objection moot.

The specification was objected to for not providing proper antecedent basis for the limitations in original claims 39 and 40. Claims 39 and 40 have been canceled, thereby making this rejection moot. Irrespective of this fact, the paragraph in the specification beginning at page 7, line 18 has been amended to provide proper antecedent basis for former original claims 39 and 40. Specifically, the text of original claims 39 and 40 have been added to the paragraph in the specification beginning at page 7, line 18. Applicants submit that the amendments to the specification do not constitute new matter.

THE SECTION 112(1) REJECTION

The examiner objected to claims 39 and 40 under 35 U.S.C. §112(1) for not being described in the specification to enable one skilled in the art to make or use the invention. Although claims 39 and 40 have been canceled by this Amendment, thereby making the rejection moot, Applicants disagree with this rejection of the claims. United States Patent Publication Nos. 2004/0093076 and 2004/0093077 disclose stents that are formed by a microelectromechanical machining process that is used to form the teeth or other indentations that are part of the ratcheting mechanism. As such, Applicants submit that one skilled in the art of manufacturing stents would understand how, at the time the present application was filed, to form a stent by a microelectromechanical machining process and to use such process to form the teeth or other indentations that are part of the ratcheting mechanism.

THE SECTION 102 REJECTION

Claims 1, 2, 4, 5, 8, 9, 12, 13, 15, 16, 19-23, 31, 32, 36, 37, 41, 42, 44, 47-49, 52, 54 and 56 were rejected under 35 U.S.C. §102(b) as being anticipated by Reich. Applicants have canceled these claims thereby making the rejection moot.

Applicants submit that the new independent claims are not anticipated by Reich. All the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich does not disclose, teach or suggest claim elements 2, 4 and 5 in the new pending claims. Furthermore, Reich does not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not anticipated or made obvious by Reich.

THE SECTION 103 REJECTION

Claims 6, 7, 10, 11, 27, 29, 30, 43, 45, 46, 50, 51, 53, 55, 57, and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Furst and Hammond. Applicants have canceled these claims thereby making the rejection moot.

Applicants submit that these three references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims

include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich, Furst and Hammond do not disclose, teach or suggest claim elements 2 and 4 of the new pending claims. Furthermore, Reich, Furst and Hammond do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich, Furst and Hammond.

Claim 14 was rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Roorda. Applicants have canceled claim 14 thereby making the rejection moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants

submit that Reich and Roorda do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and Roorda do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and Roorda.

Claims 2, 3, 17-19, 24-28 and 53 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Brauker. Applicants have canceled claims 2, 3, 17-19, 24-28 and 53 thereby making the rejection of these claims moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and Brauker do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and Brauker do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and Brauker.

Claims 32-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view

of Kennedy. Applicants have canceled claims 32-35 thereby making the rejection of these claims moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and Kennedy do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and Kennedy do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and Kennedy.

Claims 38-40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of McGuinness. Applicants have canceled claims 38-40 thereby making the rejection of these claims moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote

endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and McGuinness do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and McGuinness do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and McGuinness.

Applicants further submit that in addition to the fact that none of the cited references disclose, teach or suggest the limitations of the new pending independent claims, several of the pending dependent claims also include limitations that are not disclosed, taught or suggested by the cited art of record. Non-limiting examples of such dependent claims include claims 61-75, 78-92 and 96-115.

Applicants submit that all the new pending claims are in condition for allowance.

Respectfully submitted,
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